



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,684	01/10/2001	Larry L. Hood	155694-0067	3084
7590	12/23/2003		EXAMINER	
Ben J. Yorks Irell & Manella, LLP Suite 400 840 Newport Center Drive Newport Beach, CA 92660			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3739	
			DATE MAILED: 12/23/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
--------------------	-------------	-----------------------	---------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on September 5, 2003

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 11, 13-16, 18, 20-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 11, 13-16, 18, 20-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

BEST AVAILABLE COPY

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11, 13-16, and 18 are rejected under 35 U.S.C. 101 because the apparatus claims positively recite the cornea, and part of the body.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doss et al in combination with Wuchinich. Doss et al teach a device which can deliver energy at 100 KHz-10 MHZ (see column 3, lines 46-51), with a ground pad (see Figure 1, element 36 and column 3, lines 41-44), a connector arrangement as claimed (see elements 12, 16, and 20 or 12, 26 and 28 in figure 5) and a stop (see element 42 figure 5). Doss et al also teach the application of power in bursts of "about one second" (see column 3, line 50) as well as the typical corneal thickness and desired temperature ranges to heat the tissue (see column 1, lines 38-68).

Wuchinich teaches the use of a pulsed periodic damped waveform for coagulation. It would have been obvious to the artisan of ordinary skill to employ the power source and connections of Doss et al to maintain the power level at or below 1.2 watts, since the desired temperature changes to produce the effects are known, and thus the appropriate wattage would also be known, Doss et al also teach the desired temperature for shrinkage of tissue and the use of RF in the claimed frequency and time exposure range to provide the shrinkage; and to employ damped waveform, since this is the waveform used for coagulation and to employ a pulse repetition rate between 4 KHz, and 12 KHz, since Wuchinich merely discloses a general pulse repetition rate; the precise repetition rate determining the temperature that the tissue will reach; and the

Art Unit: 3739

temperature for corneal shrinkage are known as taught by Doss et al, thus producing a device such as claimed.

Claims 20, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doss et al in combination with Wuchinich. The teachings of Wuchinich and Doss et al and the motivations for combination and modification thereof are essentially those already set forth above. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings to produce a method such as claimed.

Claims 13, 15, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doss et al in combination with Wuchinich as applied to claims 11, 14, and 18 are above, and further in combination with Schachar. Schachar teaches a system for heating the corneal stroma including a probe tip which is heated to heat the stroma wherein the last 300 to 600 microns is considered to be the tip and the shaft of the probe is considered a "spring beam" since its function is to help maintain contact with the tissue to be heated. It would have been obvious to the artisan of ordinary skill to either employ the connections of Doss et al in the system of Schachar, since Schachar teaches no particular power source or to employ the probe configuration of Schachar in the device of Doss et al, since this would provide a more localized application of heat to the stromal tissue and to maintain the power level at or below 1.2 watts, since the desired temperature to produce the effects are known and thus the appropriate wattage would also be known, further the exact power level and duration being dependant on the probe geometry and configuration, and the probe geometry of Schachar being the same as that of applicants probe, the power requirement would be the same, thus producing a device such as claimed.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Doss et al in combination with Wuchinich et al as applied to claims 20, 21, and 23 are above, and further in view of Schachar. The teachings of Schachar and the motivation for combination and modification thereof are essentially those already set forth regarding claims 13, 15, 16, and 18. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings to produce a method such as claimed.

Applicant argues that none of the applied references teach a probe in contact with the cornea that transmits current through current through the cornea. The examiner must disagree. The probe of Doss et al already transmits current through the cornea and the probe of Doss et al clearly contacts the corneal at surface 42 (see figure 2 and the sentence bridging columns 3 and 4).

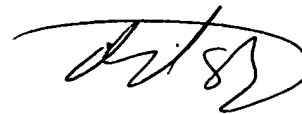
Applicant also argues that Doss et al teach away from the Schachar type probes because they can create a high surface temperature. The examiner respectfully submits that applicant has misread the Doss et al disclosure with respect to thermokeratoplasty probes. It is clear from the discussion in column 1 and the experimental comparison in column 6 of Doss et al that the thermokeratoplasty probes to which Doss et al refer are probes that contact the corneal surface. A careful reading of Schachar – e.g. lines 18-36 in column 1 reveals that the stromal contact method of Schachar seeks to remedy the same problem as discussed by Doss et al. Thus no teaching away from the Schachar device or method is fairly attributed to Doss et al.

Applicant's theory that simple D.C. current could suffice in the device of Schachar is noted, however the fact remains that Schachar teaches no particular power supply and the supply of Doss et al does suffice to provide sufficient heat to denature the cornea.

Art Unit: 3739

Applicant's arguments filed July 29, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

A handwritten signature in black ink, appearing to read 'D. M. Shay', enclosed within a large, stylized circular flourish.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

Shay/DI

November 24, 2003